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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,048	02/24/2000	GRAHAM VESEY	047763-5012	7495

9629 7590 04/09/2003

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/09/2003

46

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/424,048

Applicant(s)

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9,16-20,22-24 and 37 is/are rejected.
- 7) ☒ Claim(s) 2-8, 10-15, 25-30, 32-36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The Examiner of U.S. Patent application SN 09/424,048 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Shannan-Shah, Technology Center 1600, Art Unit 1645.
2. Applicants amendment and response, received 5/16/2002 paper # 15 are acknowledged. Claims 1, 9, 13 and 22 were amended. New claims 24-37 were added.
3. Claims 1-20 and 22-37 are pending and under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No forms PTO-892 or PTO-1449 have been submitted with this office action.

Drawings

6. The drawings are objected to by the Draftsperson under 37 CFR 1.84 or 1.152. See attached form PTO 948.

Priority

7. Priority statement is missing from specification:

This application filed under former 37 CFR 1.62 lacks the necessary reference to the prior application. A statement reading "This is a U.S.C. 371 of Application No. PCT/AU98/00368, filed 5/19/1998 and claims priority to Australian applications No. PO6962, filed on 5/19/1997

and PO8242 filed 7/25/1997." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of the parent nonprovisional application(s) should be included.

Rejection(s) Withdrawn

8. Rejection of claims 1-8 and 16-17 under 35 U.S.C. 102 (b) as being anticipated by McDonald et al. is withdrawn in view applicants amendments.

9. Rejection of claims 9-15 and 18-19 under 35 U.S.C. 103 (a) as being unpatentable over McDonald et al. in view of Riggs et al. withdrawn in view applicants amendments.

Rejection(s) Maintained

10. The rejection of claims 20, 22-23 under 35 U.S.C. 112 (first paragraph) for failing to provide an enabling disclosure because the specification lacks the complete deposit information for the clone CRY 104 is maintained. Applicants requested the examiner to hold this rejection in abeyance until allowable subject matter has been found with the understanding that the necessary information will be provided at such time. However, until the strain is deposited and all rights irrevocable removed upon the granting of the patent, this rejection is maintained.

New Grounds for Objections and Rejections

Claim Objections

11. Claim 24 is objected to under 37 CFR 1.75 as being substantial duplicates of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant application the wording are not exactly the same in all steps of the

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claimed method. However the outcome of the method on both claims are the same. Recitation of the different words does not impart any patentability weight on the claims.

New Matter Rejection

12. Claims 1, 9, 24, 31 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims now include the newly added limitation “ free from sporozoite antigens”. However, there appears to be no descriptive support in the instant specification for this added limitation. 37 CFR 1.121 requires that an amendment to the claim must have antecedent basis in the original disclosure. Therefore the new limitation in the claim is considered new matter. *In re Rasussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step or a compound from a disclosure. See MPEP 608.04.

Applicants are respectfully requested to point out to the proper descriptive support in specific part (s) of the disclosure as filed, for the newly added limitation, or to remove the new matter from the claims.

102 Rejection

13. Claims 16-19 are rejected under 35 U.S.C. 102 (b) as being anticipated by McDonald et al. (Parasitology 110: pp. 259-298, 1995).

The claims are drawn to an isolated IgG1 antibody reactive to the surface of *Cryptosporidium* oocysts produced by the method of claim 1.

McDonald et al. disclose an isolated IgG antibody was produced specifically against the surface of *Cryptosporidium* oocysts (oocysts wall) (see material and method section; specially monoclonal section). McDonald et al. do not teach IgG1 antibody. However, IgG1 will be inherent in isolated IgG antibody of McDonald et al.

Note: the examiner views this as product by a process. How the product is produced does not impart any novelty or unobviousness to a product when the same product is taught by the prior art. The products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. (reactivity to surface of *Cryptosporidium* oocysts). The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Even if applicant's product is of a higher purity than that of the prior art product, applicant's product would have been *prima facie* obvious over the product of the prior art since one of ordinary skill in the art, being motivated by the expectation of success and the attainment of greater specific activity with increased purity, could have used conventional techniques in the product art to further purify and characterize the product. Thus even if applicant's product can be shown to be of higher purity than the product of

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the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with the increased purity, greater stability and /or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration, which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the obviousness aspect of this rejection, i.e. assuming the aspect of the product's purity is relied upon.

14. Claims 1-15 and 24-37 are free from prior art.

Conclusion

14. Claims 1, 9, 16-20 and 22-24, 31 and 37 stand rejected.

15. Claims 2-8, 10-15, 25-30, 32 -36 are objected to as being dependent from the above rejected claims.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

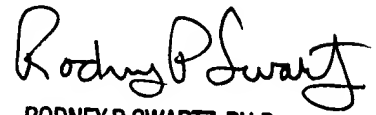


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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March 26, 2003



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER